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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/392,842	09/09/1999	SAMUEL P. SAWAN	SUR-008	1863

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/392,842

Applicant(s)

SAWAN ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58,60,62-71 and 89-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58,60,62-71 and 89-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

RD

DETAILED ACTION

Amendment filed on December 10, 2004 has been entered. Claims 58, 60, 62-71, 89-101 are pending.

Prosecution on the elected bigunide polymer specie of poly(hexamethylenebiguanide) ("PHMB"), and water-insoluble organic compound specie of methylene-bis-N,N-diglycidylaniline, ("MBDGA") as set forth in Paper No. 8, is continued.

Any rejection that is not addressed in this Office Action is considered obviated in view of the arguments that Fujiwara US Patent 6,071,866 is not a competent prior art under 35 USC §102 (e) rejection.

Double Patenting

Claims 58, 60, 62-71, 89-101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-38 of U.S. Patent No. US 6,180,584, claims 1-6 US Patent 6,030,632, claims 1-9, US Patent 5,869,072, claims 1-9, US Patent 5,817,325.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the cited patents are directed to compositions comprising a biguanide material, a metal material such as silver compounds and a cross linker, and/or methods of using such compositions to improve the antimicrobial activity of an article or a secondary formulation.

For example, claims of the patent 6,018,584 are directed to methods of providing antimicrobial activity on skin by applying the claimed invented disinfectant composition

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on a substrate (claims 1, 27-33). The instant claims differ from the patented claims only by the nature of the substrate. However, it would have been obvious to one of ordinary skill in the art at the time of invention to employ the compositions of the patented claims on suitable substrates including scrubs, skin preparations directly or through suitable carrier systems. Accordingly, the instant claims are obvious modification of the already patented claims.

Examiner noted Applicant statement indicating that an appropriate terminal disclaimer will be filed once allowable subject matter is determined.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 89, 92, 95, 98 are rejected under 35 U.S.C. 102(e) as being anticipated by Fujiwara et al US Patent 5,681,802.

The instant claims are directed to methods of treating skin comprising administering a composition comprising an organic polycationic polymer and a metallic material and forming a moisture-resistant film on the skin.

Fujiwara teaches skin-cleansing agents comprising cationic polymers and/or cationic surfactant system with a metal containing material within the scope of the instant claims (see col 3, lines 21-25; col 8, lines 19-25; col 9, lines 5-25; col 77, lines 40-60). The cationic polymer of Fujiwara can be either in the form of cationic conditioner such as polyquaternium 7, 24, or cationic surfactants (see col 5, lines 53-55; col 8, lines 19-22; compositions 3-6). The metallic compounds of Fujiwara's compositions include

sodium chloride, sodium sulfonates, or metallic sorbates as preservatives. Thus, the limitations of the compositions described in Fujiwara meets the limitations of the instantly employed compositions.

Since the compositions of Fujiwara meets all elements of the compositions employed in the step (a) of the instant claims, formation of a moisture-resistant film and the properties of the film (i.e. sweat resistant) would be an inherent function of such skin compositions of Fujiwara when it is applied to skin, because such properties or function are inseparable from the composition upon its application to skin.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 58, 60, 62-71, 89-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawan et al WO 95/17152 ('152) in view of Fujiwara US Patent 5,681,802 and Smith US Patent 5,576,006.

Instant claims are directed to methods of treating skin by (a) administering to skin a composition comprising providing antimicrobial activity on skin comprising a biguanide polymer, a metallic material and a skin compatible component and (b) forming a moisture-resistant film on the skin to provide antimicrobial activity.

Sawan '152 teaches that the cross-linking of PHMB with a water-insoluble organic compound such as MBDGA enhances the final activity. Swan also teaches the use of silver salts as a bactericidal metallic material (see pages 25-29, page 65, lines 3-20). Sawan's formulations are readily used topically directly or indirectly (see page 27

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last para – page 28, 1st para). In fact, Sawan spreads the compositions directly into the eye (see page 60, claims 29-30). Thus, it is well established in the art that silver salts of Swan are bactericidal material and that they are readily used for topical applications. Sawan does not directly teach various topical components such as preservatives, thickeners, emollients, etc... used to make topical formulations for direct skin administration.

Liquid skin cleanser compositions containing skin compatible components such as emollients, thickeners, moisturizing agents and surfactants, in the form of ointment, soap or lotion are well described in the art. Fujiwara discloses liquid skin cleanser compositions in the form of lotion or cream comprising a cationic polymer and a metallic material that falls within the scope of the instant claims as described in page 7 of the specification. (see col 5, lines 15-24). Fujiwara also teaches other skin compatible components such as lactic acid and surfactants, thickeners, pH modifiers to formulate a topical cleansing formulation. (col 7, lines 26-col 8, line 25). Fujiwara compositions are in the form of lotion, soap, cream etc.. (see col 9-11). Fujiwara fails to employ silver salts and PHMB in his composition as an additional antimicrobial agent.

Smith is complementary to Fujiwara and Sawan as it provides the state of art for preparing topical PHMB containing lotions (see col 3, line 39-col 4, line 50).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to merely combine the formulations of Sawan and Fujiwara and apply such composition directly to skin to provide antibacterial activity on skin. The ordinary skill in the art would have made motivated to combine the compositions of Sawan and

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Fujiwara, because it has been held *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980). Thus, instant claims that require no more than mixing together of two conventional antimicrobial compositions and using it topically on skin are viewed to be unpatentable over the cited prior art.

In alternative, since both PHMB and Silver salts, as described by Sawan and Smith, provide antibacterial properties, one of ordinary skill in the art at the time of invention would have been motivated to add them together to skin cleansing compositions such as those described by Fujiwara to enhance antimicrobial activity of such compositions.

Conclusion

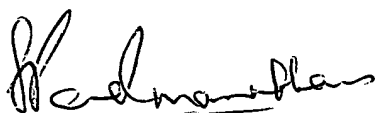
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnaz Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER